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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,866	08/07/2002	Erling Sundrehagen	7885.81USWO	8079

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EXAMINER	
ZEMAN, MARY K	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,866	SUNDREHAGEN, ERLING	
	Examiner	Art Unit	
	Mary K Zeman	1631	

-- Th MAILING DATE of this communication app ars on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 28-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 28-55 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 07 August 2002 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 8/7/02.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Notice to comply.

DETAILED ACTION

Claims 28-55 are pending in this application. Claims 1-27 were canceled by preliminary amendment.

Priority

This application is a National stage application of PCT/NO01/00480, filed 11/30/01. It is noted that Applicant claims priority to Norwegian priority document 20006130, filed 12/01/00, however, no copy of the priority application is of record in this application. Generally this priority document should be forwarded to the National Stage application by the International Bureau, however, this has not happened in this application. Applicant is requested to provide a copy of the priority application.

Information Disclosure Statement

The IDS filed 8/7/02 has been entered and considered. An initialed copy of the PTO-1449 form is included with this action. "Insulin-I181 Metabolism..." lacks a publication date.

Drawings

The drawings filed with the application are suitable to the examiner.

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. *Failure to comply with these requirements will render the reply non-responsive.*

See the specification, pages 31, 34-36, 42, 43, 54, etc and claims 33 and 52. Any peptide sequence greater than 4 residues must comply. Any oligonucleotide sequence

greater than 10 residues must comply. Applicant is encouraged to thoroughly review the specification and claims for sequences the examiner may have overlooked.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims in general do not conform to US practice. They use the term "characterized in" or "characterized by", rather than "comprising" or "consisting of". The steps of the methods are not all positive active steps as required. The claims are excessively wordy, with multiple "and" and "or" clauses which may be better represented by Markush language ("reagent selected from the group consisting of A, B, C and D"). Applicant is requested to amend the claims to conform to US practice.

Regarding claim 28, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Further in claim 28, step (a) is extremely confusing with its multiple clauses, such that it is not clear what exact steps are being taken with what reagents. In step (b) the language is confusing, and would appear to need correction to: "a mixture which when irradiated with polarized light permits the excitation of said fluorescent molecules..."

In claim 32, the way the peptide or synthetic binder is identified is not further limiting of the binder or peptide itself.

Claims 33-36 provides for the use of a reagent for quantitation of molecules, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. It

would appear that a limitation such as "the method of claim 28 wherein the reagent comprises peptides... for quantitation of CRP."

Further in claim 36, the phrase "being constituted by less that 30 amino acids" is unclear. A more suitable phrase could be "wherein the peptide is less than 30 amino acids." Claims 37 and 38 have similar defects.

Claim 41 contains the trademark/trade name Texas Red, Cy5, etc.. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe fluorescent dyes from a particular manufacturer and, accordingly, the identification/description is indefinite.

Claim 46 lacks antecedent basis in claim 28. Claim 28 does not recite a polarization instrument, such that no limitations can be added further limiting that instrument.

In claim 48, it is entirely unclear what substance is "being provided in concentrated or dry form". It would appear some words were omitted.

Claims 50-52 are vague and indefinite, as they are drawn to "A reagent of claim 49" however, claim 49 is drawn to a method, not a composition of matter. Therefore, these claims are improper. They should be made independent and recite all the appropriate limitations.

Claims 53 provides for the use of a method for quantitation of molecules, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 53 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for

example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The metes and bounds of claim 53 are further unclear, as it is unknown what substances fall within the category of "clinically related". This phrase covers perhaps the entire universe of elements, molecules, or compositions. Further, how is one to determine what living organisms are in need of what tests?

Claim 54 is vague and indefinite as it refers to a reagent according to claim 48. However, claim 48 is drawn to a method, not a reagent. Therefore, this is improper, and it is entirely unclear what substance is being referred to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28, 29, 34, 39-47, 49 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Jolley et al. (US 5,976,820).

The claims are drawn to methods of determining the concentration of an analyte in a test sample, wherein a fluorescence polarization method is used to detect binding between the labeled reagent and the analyte. The method takes place in a single stage, with no washing steps or multiple additions of reagents. The sample can be any biological fluid such as blood. The assay can be for a single analyte. The fluorescence label has an absorption above 640nm. The reagent can comprise lysing reagents or anti-coagulants. The label can be one of any number of dyes including Texas Red, Cy5, or one of the Biodypi reagents, and is covalently linked to the binding agent. The assay can be measured as a function of time. Standard curves, temperature compensation etc can be used and stored in the polarization instrument being used. The method can be used to determine the concentrations of clinically related substances.

Jolley et al. (US 5,976,820- PTO-1449) discloses an assay wherein a single reagent is added to a blood sample, and the polarization is detected as a function of time. The assay

requires no washing, absorption or detection steps. (col 2 lines 56-64, col 6 lines 53-60). The reagent comprises fluorescently labeled polypeptides or polysaccharides. (Col 3 lines 19-25) These binding agents bind to antibodies in the sample, and the change in fluorescence polarization is measured as a function of time. (col 3 lines 8-19). The choice of fluorophore can include Texas Red, BODIPY (Biodypi), etc which have emissions between 400 and 800 nm, which falls within the limits of the claim. (col 6 lines 32-53) The fluorophore is covalently attached to the binding agent. Standard curves, and temperature controls/ algorithms can be determined ahead of time and stored. (examples 1-4). The methods of Jolley et al are used to determine the concentrations of antibodies to certain pathological bacteria in biological samples. As such, this disclosure meets the limitations of the rejected claims.

Claims 28-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakayama (WO 99/13332, US Equivalent 6,432,632 B1).

The claims are drawn to methods of determining the concentration of an analyte in a test sample, wherein a fluorescence polarization method is used to detect binding between the labeled reagent and the analyte. The method takes place in a single stage, with no washing steps or multiple additions of reagents. The sample can be any biological fluid such as blood. The binding agent can be an antibody or fragment thereof. The assay can be for a single analyte, or multiple analytes. The fluorescence label has an absorption above 640nm. The reagent can comprise lysing reagents or anti-coagulants. The label can be one of any number of dyes including Texas Red, Cy5, or one of the Biodypi reagents, and is covalently linked to the binding agent. The assay can be measured as a function of time. Standard curves, temperature compensation etc can be used and stored in the polarization instrument being used. The method can be used to determine the concentrations of clinically related substances. Reagents and kits comprising the reagents are also claimed. It is noted that the kits merely require the reagent in a container.

Nakayama et al. (WO 99/13332 A1 3/18/99) was published more than a year before the priority document was filed. The WO document is not in English. US 6,432,632 is the US National Stage patent, which resulted from the WO document, and is a proper English Language equivalent. All references to column and line number are to the US Patent document.

The binding partner of Nakayama is specifically fluorescently labeled, with a dye such as rhodamine, that has absorption and emission within the claimed parameters. The labeled binding reagent is mixed with the biological sample, and the change in the fluorescence polarization is determined without further washing, adsorbing or detecting steps. (abstract) The binding reagent may be an antibody capable of binding a peptide, or a peptide capable of binding an antibody. (column 2 lines 1-65) C-reactive protein is specifically contemplated. (col 2 line 34-35) Fluorescent dyes specifically contemplated include rhodamine, cyanin, pyrene, etc. (col 5 lines 60-65). The sample may be any type of biological fluid such as blood. (col. 6 lines 65-67) Standard curves and temperature corrections can be prepared ahead of time and stored. (see examples) The methods of Nakayama can be used to determine the concentration of clinically relevant molecules in samples from living organisms. Nakayama discloses the reagents and kits comprising the reagents. As such, Nakayama meets the limitations of the claims.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. EP 0969279 A2 (Nakayama et al.) discloses the use of multiple fluorescent labels in one reaction to identify multiple analytes.

EP 0957365 A1 (Nakayama et al.) is the EP equivalent of WO 99/13332.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272-0723.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (571) 272-0722.

The Official fax number for this Art Unit is: (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz
2/6/04

MARY K. ZEMAN
PRIMARY EXAMINER
1631

NOTICE TO COMPLY WITH SEQUENCE RULES	Application No. 10/019,866	Applicant(s) SUNDREHAGEN, ERLING	
	Examiner Mary K Zeman	Art Unit 1631	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reasons:

☒ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

☐ 4. A copy of the "Sequence Listing in computer readable form has been submitted. However the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked up "Raw Sequence Listing".

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable. A Substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☐ 7. Other:

Applicant must provide:

☒ An initial or ☐ A substitute computer readable form copy of the Sequence Listing.

☒ An initial or ☐ A Substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same, and, where applicable, include no new matter, as required by 37 CFR 1.821(e), (f), or (g) or 1.825(b) or (d).

FOR QUESTIONS PLEASE CONTACT:

Rules Interpretation (703) 308-4216
CRF Submission Help (703) 308 4212
PatentIn software help (703) 308 6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE